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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,863	12/31/2001	Bruce Robie	Implex-13	4928
28581	7590	12/21/2004	EXAMINER	
DUANE MORRIS LLP			PHILOGENE, PEDRO	
PO BOX 5203				
PRINCETON, NJ 08543-5203			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 12/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,863

Applicant(s)

ROBIE ET AL.

Examiner

Pedro Philogene

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 15-17 and 21-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 15, 16, 21, 23 and 25-34 is/are rejected.
- 7) ☒ Claim(s) 17 and 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

REOPEN PROSECUTION

In view of the appeal brief filed on 10/04/04, PROSECUTION IS HEREBY REOPENED. A new ground of rejections is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims, 1,15,16,23,25,29 are rejected under 35 U.S.C. 102(e) as being anticipated by Mehdizadeh (6,030,390).

With respect to claim 1, Mehdizadeh discloses an instrument system for preparing a disc space between adjacent vertebral bodies to receive a repair device, the

Art Unit: 3732

instrument system comprising: at least one distractor (27) including a tapered body section (31) for distracting the vertebral bodies in a manner that restores natural lordosis of the lumbar and cervical spines; as set forth in column 3, lines 4-31; the tapered body section formed by an end wall, as best seen in FIGS.4,6,8, a first pair of opposing walls portions (32), as set forth in column 3, lines 19,20, converging toward the end wall; and a second pair of opposing wall portions (36) converging toward the end wall, as set forth in column 3, lines 20-30.

With respect to claim 15, Mehdizadeh discloses a distractor for use in a system that prepares a disc space between adjacent vertebral bodies to receive a repair device, the distractor (27) comprising a tapered body section (31) for distracting the vertebral bodies in a manner that restores natural lordosis of the lumbar and cervical spines; as set forth in column 3, lines 4-31; the tapered body section formed by an end wall a first pair of opposing walls portions (32) as set forth in column 3, lines 19-20 converging toward the end wall; and a second pair of opposing wall portions (36) converging toward the end wall, as set forth in column 3,, lines 20-30.

With respect to claims 16,23,25,29, Mehdizadeh discloses all the limitations, as set forth, for example a connector section (29) for coupling a handle to the distractor, and a female coupling element (16).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 3732

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21,22, 26-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehdizadeh (6,030,390) in view of Burkus et al (6,648,895).

With respect to claims 21,22,26-34, it is noted that Mehdizadeh teaches all the limitations, except for a female coupling member formed by a T-Shape slot defining inwardly facing locking flanges; as claimed by applicant. However, in a similar art, Burkus et al evidences the use of a female coupling member formed by a T-shape slot defining inwardly facing locking flange configured to receive the flange posts of the distractor and drive the distractor into the disc space.

Therefore, given the teaching of Burkus et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the female coupling member of the device of Mehdizadeh, as taught by Burkus et al to provide a device with a T-shape slot defining inwardly facing locking flange configured to receive the flange posts of the distractor and drive the distractor into the disc space.

As to the grooves on the pair of wall portions, as claimed by applicant; Burkus et al evidence that such a groove would have been obvious to engage the vertebral endplates and resist movement of distractor tip in the disc space.

Therefore, given the teaching of Burkus et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pair of wall portions of Mehdizadeh, as taught by Burkus et al to provide a surface to engage the vertebral endplates and resist movement of the distractor tip in the disc space.

Allowable Subject Matter

Claims 17,24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Amendment

Applicant's arguments, see Appeal brief, filed 10/04/04, with respect to claims 1,15,17, 21-34 have been fully considered and are persuasive. The final rejection of these claims has been withdrawn.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

6,824,565	11-2004	Muhanna et al.
6,224,599	05-2001	Baynham et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (571) 272-4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3732

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pedro Philogene
December 16, 2004


PEDRO PHILOGENE
PRIMARY EXAMINER